



**NFPA**

*The Food Safety People*

NATIONAL

FOOD

PROCESSORS

ASSOCIATION

November 1, 1999

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane  
Rm. 1061  
Rockville, Maryland 20852

**Re: Docket No. 99N-3089; Draft Affirmative Agenda for International Activities – Center for Food Safety and Applied Nutrition; Request for Comments; 64 Federal Register 500518, September 17, 1999.**

Dear Sir or Madam:

The National Food Processors Association (NFPA) welcomes the opportunity to provide comments on *CFSAN's Draft Affirmative Agenda for International Activities* and agrees that CFSAN must establish priorities that are consistent with FDA's mission and resources in order to respond appropriately to the demands of a changing global market place.

NFPA is the voice of the \$460 billion food processing industry on scientific and public policy issues involving food safety, nutrition, technical and regulatory matters and consumer affairs. NFPA's three laboratory centers, its scientists and professional staff represent food industry interests on government and regulatory affairs and provide research, technical assistance, education, communications and crisis management support for the Association's U.S. and international members, who produce processed and packaged foods, drinks and juices. NFPA members export and import food products globally and have an interest in international trade policy.

Even though FDA is not considered a U.S. "trade" agency, the increasing dependence of the U.S. economy on world markets, consumers' demand for a growing variety of imported foods and the new influence on domestic policy imposed by the WTO Agreements no longer allow any U.S. Agency to assume an "isolationist" posture in developing U.S. regulation. The commitment of CFSAN's scientific and regulatory expertise is critical to assure that international standards continue to be based on sound science, that other national standards are developed and enforced in a manner that enhances global food safety, and that U.S. standards are not inappropriately challenged by our trading partners. Strong scientific leadership in the international arena is the key to protecting the health of American consumers, strengthening international food standards and enhancing foreign regulatory systems.

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Specifically related to the document, the "factors" CFSAN has identified underlying the Agency's international principles are appropriate. However, NFPA is concerned by CFSAN's continued stress on "consistency with available resources." Resource restrictions are common in both the private and public sectors and do help to direct priorities and activities. NFPA does not believe available resources should dictate international "principles." If CFSAN's "principles" are determined by available resources, perhaps CFSAN should be more aggressively seeking additional and/or alternative sources of funding.

With regard to alternative sources of funding for international work, NFPA and other members of the Food Industry Codex Coalition (FICC) have worked with the Administration and members of Congress to achieve dedicated funding for U.S. activities related to Codex Alimentarius. Industry representatives worked with the U.S. Codex staff to develop a budget proposal of \$3.2 million that takes into consideration the reimbursement to various U.S. agencies for travel and staff time in order to ensure that the best expertise represents U.S. interests in Codex Alimentarius. Language in the Fiscal Year 2000 Agricultural Appropriations bill indicates the growing recognition by Congress of the importance of the Agencies international activities. Hopefully, line item funding for U.S. Codex activities will be part of the FY 2001 budget and may be helpful in strengthening CFSAN's role in Codex work.

Additionally, NFPA commends CFSAN for recognizing the growing importance of the Center's participation in international issues and agrees that CFSAN has correctly identified most of the issues and activities of importance. However, the "affirmative agenda" fails to clearly identify priority work within broadly generalized categories. NFPA hopes these comments can provide some specific guidance to CFSAN to develop "A" list priorities for the next three years.

#### **Dissemination of CFSAN's Science Base**

First, the "Development, Maintenance, and Dissemination of CFSAN's Science Base" is CFSAN's **first** priority domestically and internationally. It is precisely CFSAN's science base that lends credibility to all of CFSAN's international activities: in Codex Alimentarius, in trade related activities, and in the evaluation of equivalence. CFSAN's scientific expertise is critical in order to "provide scientific leadership," not only in such "international technical committees as JECFA ..." but in bilateral and multilateral negotiations, import and export protocol and a multitude of technical committees. Recognizing the increasing lack of confidence in the EU's regulatory system (particularly as it relates to food safety), the U.S. FDA is becoming the single internationally recognized reputable food safety agency making FDA leadership even more important.

NFPA strongly agrees that CFSAN has a critical role to strengthen the scientific foundation of international food standards. U.S. trade interests are increasingly

challenged by EU's attempt to impose the precautionary principle and to introduce factors other than science into the decision making process for international food standards. FDA must work with other U.S. agencies to communicate the importance of maintaining the sound science base of the Sanitary and Phytosanitary Agreement, and to educate other nations on the principles of risk management.

### **Codex Alimentarius**

NFPA has filed numerous comments to urge CFSAN to prioritize efforts to improve international food safety standards through Codex Alimentarius. This effort is critical to enhance food safety standards globally as well as to facilitate trade. Since 1962, countries have developed, by consensus, many guidance documents on food safety and wholesomeness. These consensus documents are often adopted as regulations by developing nations and they are usually felt to provide standards that provide an appropriate level of protection for U.S. consumers. New U.S. leadership of Codex Alimentarius provides an opportunity to assure that Codex standards are based on sound science and risk assessment and that political interests do not compromise food safety.

NFPA urges CFSAN's continued strong participation in the Codex process. CFSAN must strengthen its leadership in Codex, dedicate additional resources and provide more training for the delegates. Delegates must view Codex as a priority. Strong and committed leaders can help to increase transparency, assuring that documents are prepared and circulated well in advance of the sessions to ensure the highest degree of technical accuracy in the U.S. positions and allow an opportunity to communicate those positions to other delegations.

NFPA agrees that CFSAN has appropriately identified key Codex Committees on which to focus priority. NFPA views the work of the newly established Ad Hoc Task Force on Foods Derived from Biotechnology as critical to ensure continued trade in these products and the future of this new technology. NFPA encourages CFSAN to also be prepared to provide scientific expertise to the U.S. delegation to the Ad Hoc Task Force on Fruit and Vegetable Juices as necessary. Even though the initial terms of reference for this Task Force appear restricted to reviewing and simplifying the existing commodity standards, opposing perspectives are already emerging that may threaten U.S. trade interests and/or food safety. U.S. fruit juices are an important export product and trade in this product is not without controversy. Many U.S. juices and blended products are fortified with vitamins and minerals, a practice not largely supported by the European Union. Juice pasteurization, generally supported by the U.S. juice industry, is not necessarily an international practice and opposing views may impact the safety and quality of products from other nations. Finally, NFPA urges CFSAN's continued strong participation in the development of standards and codes of practice for seafood products by the Codex Committee on Fish and Fishery Products

Codex also provides an important forum to harmonize equivalency criteria, food certification and "enhance the safety of imported foods at their source." All of these are appropriately identified CFSAN priorities.

New organization and leadership in the U.S. Codex office has enhanced the U.S. role in Codex. Nevertheless, interagency support and cooperation is key to communication a strong and consistent U.S. position. CFSAN's active participation in the Codex Steering Committee will facilitate that objective.

### **Equivalency Evaluations and Criteria**

NFPA believes that recognition of equivalence between nations will ultimately elevate food safety standards internationally while simultaneously minimizing resource intensive procedures. FDA should issue a final rule implementing its proposed draft criteria for the determination of equivalence published in 1997. FDA should endeavor to advance mutual recognition and equivalency agreements with our key trading partners for products that are widely traded. Particularly, the equivalency agreement with Canada on seafood products should be concluded promptly.

Equivalency is also being addressed in the Codex Committee on Food Import Export Certification and Inspection Systems (CCFICS). NFPA was disappointed by the failure of the Codex Commission to move the CCFICS draft guidelines into the Codex step process. Strong U.S. leadership, working with the other QUAD countries is needed to communicate the importance of harmonized international guidelines to our trading partners.

### **Certification**

Product certification, although broadly accepted in international trade, is frequently used inappropriately to discourage imports and protect domestic industry. Certification imposes unnecessary economic and documentation burdens on exporters and regulators, is not science based and (more often than not) serves no useful purpose. NFPA agrees that it is necessary for CFSAN to develop "alternative methods" to the resource intensive issuance of certificates in a manner that will facilitate trade in U.S. products while continuing to provide satisfactory health attestation to our trading partners.

However, NFPA believes that CFSAN's focus should be on working with other nations to eliminate or minimize certification requirements. Alternative mechanisms such as delegating authority to other public or private sector organizations will do nothing to address the core problems in certification. Such "alternatives" may, in fact increase product costs and complicate efforts to resolve basic concerns. Appropriate alternatives are plant listings, memorandums of understanding and equivalency agreements.

Certification is also being addressed in CCFICS. Strong U.S. leadership in this area can help develop harmonized international guidelines that provide for (1) transparency; (2) consistency with existing regulatory requirements; (3) attestation to genuine health or safety concerns; (4) efficiency and timeliness; and (5) protection of proprietary information without unnecessarily increasing product costs.

NFPA also urges CFSAN and U.S. trade agencies to engage in bilateral or multilateral negotiations with other nations to develop harmonized certification procedures and import protocol. The technical working groups of the NAFTA SPS committee are excellent forums for this dialogue. In fact, NFPA is very pleased that the FAS and FDA have recently initiated these discussions specifically as they relate to trade in shelf stable processed products and seafood among the NAFTA countries.

#### **NAFTA and FTAA Technical Committees and Working Groups**

The increasing cross border trade with our NAFTA partners combined with economic recession in the Asian Pacific countries and trade disputes with the EU demand that the U.S. take a more aggressive leadership role to facilitate trade between the nations in the Western hemisphere. The technical working groups of NAFTA and the FTAA provide excellent forums to initiate steps towards harmonizing standards. These comments previously mention the initiative towards harmonizing import protocol and certification among NAFTA countries. The NAFTA seafood working group is also working towards expanding the FDA HACCP Guidelines into NAFTA Guidelines. Other possible initiatives to address in such forums may be: harmonized approval procedures for food additive approvals, safety assessments for products of biotechnology or other new technologies; product recall and traceability procedures; and harmonized Codex positions. These working groups could also develop common positions for the work of the WTO SPS Committee.

Agreements developed through these forums could be significant as an initial step towards harmonized international standards. NFPA does not believe FDA has taken full advantage of the opportunity such technical working groups could provide. NFPA encourages CFSAN to provide the leadership for proactive working agendas for these technical groups.

#### **International Trade Agreements**

Attesting to the safety of U.S. foods is an important priority for CFSAN. Recently, NFPA and other organizations have urged FDA to more aggressively communicate the Agency's safety and review process related to food products of biotechnology. Better communication by all parties could have contributed immensely to consumer understanding and confidence in these new products. NFPA continues to urge FDA and other U.S. agencies to speak out strongly on the rigors of the U.S. process.

NFPA agrees FDA must provide appropriate scientific/technical support in food related trade disputes and negotiations. NFPA also believes FDA should take a more proactive stance to review and comment on notifications from the World Trade Organization (WTO) with respect to Sanitary Phytosanitary (SPS) and Technical Barriers to Trade (TBT) issues to better assist USDA in identifying potential barriers to trade in food products. Identification of trade barriers is critical in country-to-country negotiations. Efficient interagency cooperation is important to capitalize on an important opportunity to correct inappropriate food standards before trade disruptions or public health issues result. Ongoing interagency communication on standards issues will help to achieve consistent U.S. messages to help our trading partners address SPS and TBT concerns.

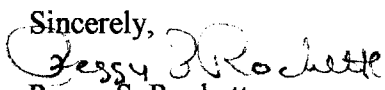
### Summary

In conclusion, NFPA commends CFSAN for recognizing the increasing importance of U.S. leadership in global food safety issues and harmonizing international standards. CFSAN's science base provides credibility to all U.S. international issues related to trade in food products. CFSAN, in the "Affirmative Agenda" has clearly recognized important international priorities. Within the next three years, NFPA encourages CFSAN to:

1. Work with other agencies to strengthen U.S. leadership in Codex Alimentarius and to maintain the science base of international food standards and the SPS Agreement;
2. Finalize FDA's criteria for evaluating equivalence and aggressively seek to conclude equivalency agreements with important trading partners for key products; work through CCFICS to move harmonized equivalence criteria forward internationally;
3. Work through interagency, as well as bilateral and multilateral fora to develop alternatives for certification that minimize resource intensive operations and are less disruptive to trade;
4. Take advantage of the technical working groups within NAFTA and FTAA to become proactive in resolving food safety and trade concerns within the western hemisphere;
5. Become more aggressive in communicating the safety of U.S. foods, specifically as related to FDA safety assessment of products of biotechnology;
6. Capitalize on the opportunity provided by WTO notifications to review and comment on issues before they become barriers to U.S. food products.

NFPA appreciates your consideration of these comments and welcomes the opportunity to work with you on any of these important international issues.

Sincerely,



Peggy S. Rochette

Director of International Affairs.